required by, and any inventory or seizure made shall comply with the requirements of, section 510(d) (3) of the Act (21 U.S.C. 880(d)(3)). The inspection shall begin as soon as is practicable after the issuance of the administrative inspection warrant and shall be completed with reasonable promptness. The inspection shall be conducted during regular business hours and shall be completed in a reasonable manner.

### § 1316.12 Refusal to allow inspection with an administrative warrant.

If a registrant or any person subject to the Act refuses to permit execution of an administrative warrant or impedes the inspector in the execution of that warrant, he shall be advised that such refusal or action constitutes a violation of section 402(a)(6) of the Act (21 U.S.C. (a)(6)). If he persists and the circumstances warrant, he shall be arrested and the inspection shall commence or continue.

## §1316.13 Frequency of administrative inspections.

Except where circumstances otherwise dictate, it is the intent of the Administration to inspect all manufacturers of controlled substances listed in Schedules I and II and distributors of controlled substances listed in Schedule I once each year; and to inspect all distributors of controlled substances listed in Schedules II through V and manufacturers of controlled substances listed in schedules III through V once every 3 years.

#### Subpart B—Protection of Researchers and Research Subjects

AUTHORITY: 21 U.S.C. 830, 871(b).

#### §1316.21 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term *investigative personnel* includes managers, Diversion Investigators, attorneys, analysts and support personnel employed by the Drug Enforcement Administration who are involved in the processing, reviewing and analyzing of declarations and other relevant documents or data relative to

regulated transactions or are involved in conducting investigations initiated pursuant to the receipt of such declarations, documents or data.

(b) The term *law enforcement personnel* means Special Agents employed by the Drug Enforcement Administration who, in the course of their official duties, gain knowledge of information which is confidential under such section.

[54 FR 31670, Aug. 1, 1989]

#### §1316.22 Exemption.

- (a) Any person who is aggrieved by a disclosure of information in violation of subsection (c)(1) of Section 310 of the Controlled Substances Act (21 U.S.C. 830) may bring a civil action against the violator for appropriate relief.
- (b) Notwithstanding the provision of paragraph (a), a civil action may not be brought under such paragraph against investigative or law enforcement personnel of the Drug Enforcement Administration.

[54 FR 31670, Aug. 1, 1989]

# § 1316.23 Confidentiality of identity of research subjects.

- (a) Any person conducting a bona fide research project directly related to the enforcement of the laws under the jurisdiction of the Attorney General concerning drugs or other substances which are or may be subject to control under the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) who intends to maintain the confidentiality of the identity of those persons who are the subjects of such research may petition the Administrator of the Drug Enforcement Administration for a grant of confidentiality: *Providing*, That:
- (1) The Attorney General is authorized to carry out such research under the provisions of Section 502(a) (2-6) of the Controlled Substances Act of 1970 (21 U.S.C. 872(a) (2-6)); and the research is being conducted with funds provided in whole or part by the Department of Justice: or
- (2) The research is of a nature that the Attorney General would be authorized to carry out under the provisions of Section 502(a) (2-6) of the Controlled Substances Act (21 U.S.C. 872(a) (2-6),